

**AUG - 8 2008**

**510(k) Summary for  
Dimension Vista® System TRF Flex® reagent cartridge  
Dimension Vista® System Protein 1 Calibrator  
Dimension Vista® System Protein 3 Control**

This summary of 510(k) safety and effectiveness information is being submitted in accordance  
with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K081299

**1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

**Manufacturer:** Dade Behring Marburg GmbH  
A Siemens Company  
Emil-von-Behring Str. 76  
35041 Marburg, Germany

**Contact Information:** Siemens Healthcare Diagnostics Inc.  
500 GBD Drive  
Newark, Delaware 19702  
Attn: Radames Riesgo  
Tel: 305.480.7558  
Fax: 305.552.5288

**Preparation date:** May 7, 2008

**2. Device Name:** Dimension Vista® System TRF Flex® reagent cartridge  
Dimension Vista® System Protein 1 Calibrator  
Dimension Vista® System Protein 3 Control

**Classification:** Class II; Class II; Class I  
**Product Code:** DDG; JIX; JJY  
**Panel:** Immunology (82) and Clinical Chemistry (75)

**3. Identification of the Legally Marketed Device:**

Dade Behring N Antisera to Human Transferrin-- K053075  
Dade Behring N Protein Standard SL -- K012470  
Dade Behring N/T Protein Control LC -- K032237

#### 4. Device Descriptions:

##### **Dimension Vista® System TRF Flex® reagent cartridge**

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

##### **Dimension Vista® System Protein 1 Calibrator**

Protein 1 Calibrator is a multi-analyte, liquid human serum based product containing  $\alpha_1$ -acid glycoprotein,  $\alpha_1$ -antitrypsin,  $\beta_2$ -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, hemopexin, homocystine, immunoglobulin A, immunoglobulin E, immunoglobulin G, immunoglobulin G subclass 1, immunoglobulin G subclass 2, immunoglobulin G subclass 3, immunoglobulin G subclass 4, immunoglobulin M, prealbumin, retinol binding protein, soluble transferrin receptor and transferrin.

##### **Dimension Vista® System Protein 3 Control**

Protein 3 Control is a multi-analyte, lyophilized, polygeline and rabbit plasma albumin based product containing  $\alpha_1$ -Microglobulin, albumin, immunoglobulin G and transferrin.

#### 5. Device Intended Uses:

##### **Dimension Vista® System TRF Flex® reagent cartridge:**

The TRF method is an *in vitro* diagnostic test for the quantitative measurement of transferrin in human serum, heparinized plasma, EDTA plasma or urine on the Dimension Vista® System. Measurements of transferrin aid in the diagnosis of malnutrition, acute inflammation, infection, and iron deficiency anemia.

##### **Dimension Vista® System Protein 1 Calibrator:**

Protein 1 Calibrator is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin G (IGG) [serum/plasma] and (IGG-C) [cerebrospinal fluid]
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin G Subclass 1 (IGG1)
$\beta_2$ -Microglobulin (B2MIC)	Immunoglobulin G Subclass 2 (IGG2)
C3 Complement (C3)	Immunoglobulin G Subclass 3 (IGG3)
C4 Complement (C4)	Immunoglobulin G Subclass 4 (IGG4)
Ceruloplasmin (CER)	Immunoglobulin M (IGM)
Haptoglobin (HAPT)	Prealbumin (PREALB)
Hemopexin (HPX)	Retinol Binding Protein (RBP)
Homocystine (HCYS)	soluble Transferrin Receptor (STFR)
Immunoglobulin A (IGA)	Transferrin (TRF) [serum/plasma] and (TRF-U) [urine]
Immunoglobulin E (IGE)	

**Dimension Vista® System Protein 3 Control:**

PROT3 CON is an assayed, low level intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the determination of  $\alpha_1$ -Microglobulin (A1MIC), specialty Albumin (sALB\*), Immunoglobulin G (IGG -C\*), Microalbumin (MALB) and Transferrin (TRF-U\*\*).

\* For Cerebrospinal fluid (CSF)

\*\* For urine

**6. Medical devices to which equivalence is claimed and comparison information:**

The Dimension Vista® System TRF assay, Dimension Vista® System Protein 1 Calibrator and Dimension Vista® System Protein 3 Control are substantially equivalent and have the same intended uses to the Dade Behring N Antisera to Human Transferrin (K053075), Dade Behring N Protein Standard SL (K012470) and Dade Behring N/T Protein Control LC (K032237), respectively.

**7. Device Performance Characteristics:**

The Dimension Vista® System TRF assay was compared to the Dade Behring N Antisera to Human Transferrin assay on the BN ProSpec® System by evaluating urine samples with concentrations ranging from 2.0 to 24.4 mg/L. Regression analysis of these results yielded the following equation:

**Method Comparison Study**

Comparative Method	n	Slope	Intercept	Correlation Coefficient
N Antisera to Human Transferrin on the BN ProSpec®	63	0.983	- 0.059	0.991

**8. Conclusion:**

The modified Dimension Vista® System TRF assay, modified Dimension Vista® System Protein 1 Calibrator and modified Dimension Vista® System Protein 3 Control are substantially equivalent to the legally marketed devices based upon the correlation studies and the information above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.  
c/o Mr. Radames Riesgo  
Regulatory Affairs and Compliance Manager  
500 GBC Drive  
MS 514  
Newark, DE 19702

**AUG - 8 2008**

Re: k081299

Trade/Device Name: Dimension Vista® System TRF Flex Reagent Cartridge  
Dimension Vista® System Protein 1 Calibrator  
Dimension Vista® System Protein 3 Control with models K7072, KC710  
and KC775

Regulation Number: 21 CFR 866.5880

Regulation Name: Transferrin immunological test system

Regulatory Class: Class II

Product Code: DDG, JIX, JJY

Dated: July 7, 2008

Received: July 8, 2008

Dear Mr. Riesgo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Maria M. Chan". The signature is fluid and cursive, with the first name "Maria" and last name "Chan" being clearly legible, and the middle initial "M." also visible.

Maria M. Chan, Ph.D.  
Acting Division Director  
Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K081299

**Device Name:**

Dimension Vista® System TRF Flex® reagent cartridge

**Indications for Use:**

The TRF method is an *in vitro* diagnostic test for the quantitative measurement of transferrin in human serum, heparinized plasma, EDTA plasma or urine on the Dimension Vista® System. Measurements of transferrin aid in the diagnosis of malnutrition, acute inflammation, infection, and iron deficiency anemia.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Maria M. Chan*  
Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

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## Indications for Use

510(k) Number (if known): K081299

**Device Name:**

Dimension Vista® System Protein 3 Control

**Indications for Use:**

PROT3 CON is an assayed intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the determination of  $\alpha_1$ -Microglobulin (A1MIC), specialty Albumin (sALB\*), Immunoglobulin G (IGG -C\*), Microalbumin (MALB) and Transferrin (TRF-U\*\*).

\* For Cerebrospinal fluid (CSF)

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Office of In Vitro Diagnostic  
Device Evaluation and Safety

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## Indications for Use

510(k) Number (if known): K081299

**Device Name:**

Dimension Vista® System Protein 1 Calibrator

**Indications for Use:**

PROT1 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin G (IGG) [serum/plasma] and (IGG-C) [cerebrospinal fluid]
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin G Subclass 1 (IGG1)
$\beta_2$ -Microglobulin (B2MIC)	Immunoglobulin G Subclass 2 (IGG2)
C3 Complement (C3)	Immunoglobulin G Subclass 3 (IGG3)
C4 Complement (C4)	Immunoglobulin G Subclass 4 (IGG4)
Ceruloplasmin (CER)	Immunoglobulin M (IGM)
Haptoglobin (HAPT)	Prealbumin (PREALB)
Hemopexin (HPX)	Retinol Binding Protein (RBP)
Homocysteine (HCYS)	soluble Transferrin Receptor (STFR)
Immunoglobulin A (IGA)	Transferrin (TRF) [serum/plasma] and
Immunoglobulin E (IGE)	(TRF-U) [urine]

*Maria M. Chan*  
Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K081299

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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